



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,331	03/25/2004	Kit S. Lam	02307W-131510US	1374
20350	7590	09/28/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			LIU, SUE XU	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/811,331

Applicant(s)

LAM ET AL.

Examiner

Sue Liu

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-21 and 28, drawn to a method for preparing a library of compounds using various synthesis templates, classified variously, for example in class 435, subclass DIG 49.

Group 2. Claim 22, drawn to a library of compounds comprising compounds and their synthesis templates, classified variously, for example in class 435, subclass DIG 34.

Group 3. Claim 23, drawn to a library of compounds comprising cleaved compounds, classified variously, for example in class 536, subclass 26.12.

Group 4. Claims 24 and 25, drawn to a method of identifying a compound attached to its synthesis template that binds to a target, classified variously, for example in class 435, subclass DIG 14.

Group 5. Claims 26 and 27, drawn to a method of identifying a compound cleaved from its synthesis template that binds to a target, classified variously, for example in class 544, subclass 283.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups 2 and 3 are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the

Art Unit: 1639

intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as a library of products for screening binding partners such as specific proteins, or to be useful as part of a protein sandwich assay, and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

3. Inventions of Groups 1, 4 and 5 are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case the different inventions in Groups 1, 4 and 5 direct to various distinct methods, because they use different steps, require different reagents and/or will produce different results. The invention of Groups 4 and 5 direct to methods of identifying a compound that binds to a target, and requires the step and/or reagent of binding to a specific target, which is step and/or reagent that is not required by Group 1 method. Group 4 method requires a compound that is not cleaved from its synthesis template, which is not required by Group 5 method. Art anticipating or rendering obvious each of the above identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups 1, 4 and 5 have different issues regarding patentability and enablement and represent patentably distinct subject matter. Thus, inventions of Groups 1, 4 and 5 are distinct, and restriction between the groups is proper.

4. Inventions of Groups (2 and 3) and (4 and 5) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Groups (2 and 3) inventions are drawn to different compounds, which can be used in different processes such as Groups 1, 4 and 5 methods. In addition, the products of Groups 2 and 3 can be used in different processes from Groups 4 and 5 methods. For example, the composition of Groups 2 and 3 can be used in protein sandwich assays, protein inhibition assays, and to synthesize new compounds. Thus, restriction between the groups is proper.

5. Inventions Groups (2 and 3) and Group 1 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products of Groups 2 and 3 can be made by isolating biological macromolecules such as protein fragments or DNA fragments from biological systems (such as bacteria), and then attached to solid support comprising various functional groups. The products of Groups 2 and 3 can also be generated by combinatorial chemical synthesis, and then attached to solid support comprising various reactive groups. Thus, restriction between the groups is proper.

6. Therefore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods and products will require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches will be coextensive. Therefore, these do create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

7. This application contains claims directed to the following patentably distinct species of the claimed invention. For the elected Group of invention, applicants are requested to further elect **a single ultimate species for each** of the following:

A.) A single specific synthesis template as specified by the following (Required for Groups 1-5):

i.) A single specific solid support. Applicants are requested to specify each of the interior and the exterior portions, i.e. specify each of the selected reactive functional groups for each of the interior and the exterior portions. Applicants are requested to specify all **bonds** and **atoms** for each of the selected reactive groups. Applicants are also requested to provide structural drawings for the selected solid support indicating each of the reactive functional groups.

ii.) A single specific scaffold. Applicants are requested to specify the specific number of scaffold functional groups. Applicants are requested to specify all **bonds** and **atoms** for each of the selected scaffold functional groups. Applicants are also requested to provide structural drawings for each of the scaffold functional groups.

iii.) A single specific scaffold linker. Applicants are requested to specify all **bonds** and **atoms** for the selected scaffold linker. Applicants are also requested to provide structural drawings for the scaffold linker.

iv.) A single specific number of coding tag precursors. Applicants are requested to specify all **bonds** and **atoms** for each of the selected coding tag precursors, i.e. specify each selected coding functional group and coding linker. Applicants are also requested to provide structural drawings for each of the selected coding tag precursors.

v.) Applicants are also requested to provide the specific chemical structure drawing corresponding to the selected synthesis template indicating the specific positions, bonds, and atoms of each of the above listed components.

vi.) Applicants are also requested to provide chemical names including common, IUPAC and synonyms of all the selected compounds for the above listed components.

vii.) Applicants are also requested to indicate on which structural formula and claim the elected synthesis template reads. (e.g. Formula Ia)

B.) A single specific “first reactive component”. Applicants are requested to specify all **bonds** and **atoms** for the selected “first reactive component”. Applicants are also requested to

Art Unit: 1639

provide structural drawings for the selected “first reactive component”. Applicants are also requested to specify the “first scaffold building block”, and the “first coding building block” that are formed with the selected “first reactive component”. (Required for Groups 1-5)

C.) A single specific “successive reactive component”. Applicants are requested to specify all **bonds** and **atoms** for the selected “successive reactive component”. Applicants are also requested to provide structural drawings for the selected “successive reactive component”. Applicants are also requested to specify the “subsequent scaffold building block”, and the “subsequent coding building block”. (Required for Groups 1-5)

D.) A single specific “first compound” formed, i.e. specify each bond and atom of the first compound. (Required for Groups 1-5)

E.) A single specific number of additional reactive components. Applicants are also requested to specify each of the elected additional reactive components, i.e. specify each bond and atom of the reactive components. (Required for Groups 1-5)

F.) A single specific reaction. (see Claim 4) (Required for Groups 1-5)

G.) A single specific compound formed by method of Claim 1. Applicants are requested to specify all **bonds** and **atoms** for the selected compound. Applicants are also requested to provide structural drawings for the selected compound. (Required for Groups 1-5)

H.) A single specific compound formed by method of Claim 2. Applicants are requested to specify all **bonds** and **atoms** for the selected compound. Applicants are also requested to provide structural drawings for the selected compound. (Required for Groups 1-5)

I.) A single specific target. (Required for Groups 4 and 5)

Art Unit: 1639

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purpose as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-28 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

Art Unit: 1639

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

Art Unit: 1639

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
9/15/06


MARK SHIBUYA, PH.D.
PATENT EXAMINER